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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,636	03/29/2004	Nehal Mohamed	ELI-029	3487

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EXAMINER	
SHAHNAN SHAH, KHATOL S	
ART UNIT	PAPER NUMBER
1645	
MAIL DATE	DELIVERY MODE
05/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/812,636	MOHAMED ET AL.	
	Examiner	Art Unit	
	Khatol S. Shahnan-Shah	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 65-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,65-74 and 76* is/are rejected.

7)☒ Claim(s) *75* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

1. The amendment filed 12/20/2007 has been entered into the record. Claims 63 and 64 have been cancelled. Claims 1, 67-69, 71 and 76 have been amended. Claims 1 and 65-76 are pending and under examination.

Rejections Moot

2. Rejection of claim 64 under 35 U.S.C. 102(b) as being anticipated by Mohamed et al., made in paragraph 9 of the office action mailed 6/22/2007 is moot in view of cancellation of said claim.

3. Rejection of claim 63 under 35 U.S.C. 103(a), made in paragraph 11 of the office action mailed 6/22/2007 is moot in view of cancellation of said claim.

Rejections Withdrawn

4. Rejection of claims 1, 65, 67, 68, 71 and 72 under 35 U.S.C. 102(b) as being anticipated by Taylor et al., made in paragraph 7 of the office action mailed 6/22/2007 is withdraw in view of applicants' amendments of 12/20/2007.

5. Rejection of claims 1, 65, 66, 67, 68, 71, 72 and 74 under 35 U.S.C. 102(b) as being anticipated by Lindorfer et al., made in paragraph 8 of the office action mailed 6/22/2007 is withdraw in view of applicants' amendments of 12/20/2007.

6. Rejection of claims 1, 65, 67, 68, 69, 70, 71, 72, 74 and 72 under 35 U.S.C. 102(e) as being anticipated by Mohamed et al., made in paragraph 9 of the office action mailed 6/22/2007 is withdraw in view of applicants' amendments of 12/20/2007.

7. Rejection of claims 1, 65, 66, 67, 68, 71, 72, 74 and 76 under 35 U.S.C. 103(a), made in paragraph 11 of the office action mailed 6/22/2007 is withdraw in view of applicants' amendments of 12/20/2007.

New Rejections Based on Amendment

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the

> subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindorfer et al. (Immunological Reviews 2001, vol. 183, pp. 10-24) in view of Taylor et al.(WO 01/58483).

The amended claims are drawn to a bispecific molecule comprising an anti-CR1 antibody linked to a non-neutralizing antibody that specifically binds to Staphylococcus

aureus protein A.

Lindorfer et al. teach a bispecific molecule comprising an anti-CR1 antibody linked to a non-neutralizing antibody that binds to a bacterial protein (see abstract, page 13 and figures 1 and 2).

Lindorfer et al. teach that the anti-CR1 antibody is cross-linked to the non-neutralizing antibody, and cross-linking agents (see abstract and page 11). Lindorfer et al. teach monoclonal antibodies (pages 12 and 13). Lindorfer et al. teach anti-CR1 7G9 monoclonal antibodies (see page 13). Lindorfer et al. also teach reduced immunogenicity of one or more antibodies (see page 12*).* Lindorfer et al. teach multiple full-length antibodies (see figures 2 and 3). Lindorfer et al. teach that studies in monkey models indicate that HP (heteropolymers or bispecific monoclonal antibodies) can be used to bind prototype pathogens (see page 12 Heteropolymers and IC clearance). Lindorfer et al. teach that heteropolymers or bispecific molecules can consist of a monoclonal antibody specific for CR1 that is chemically crosslinked with a monoclonal antibody specific for target pathogen (see abstract). Lindorfer et al. do not teach an antibody that recognize *Staphylococcus* aureus protein A.

Taylor et al et al. teach the effect of bispecific monoclonal antibodies on different pathogens (see example page 78); anti CR1 and 7G9 (see table 6, abstract and claims). Taylor et al et al. teach Staphylococcus aureus (see claim 39 and page 44). Taylor et al et al. teach limitations of claim 70 Fab, Fab', Fv (see pages 11, 12 and 22). Taylor et al et al. teach specific antibody for protein A (see page 18, lines 22-30).

It would have been *prima facie obvious* to one of ordinary skill in the art at the time the invention was made to combine the teachings of Lindorfer et al., a bispecific molecule comprising an anti-CR1 antibody linked to a non-neutralizing antibody that binds to a bacterial antigen with the teachings of Taylor et al, et al.

monoclonal antibodies that binds *Staphylococcus* aureus protein A to obtain a bispecific molecule comprising an anti-CR1 antibody linked to a non-neutralizing antibody that binds to *Staphylococcus* aureus protein A. One of skilled in the art would have been motivated by the teaching of Lindorfer et al. that studies in monkey models indicate that HP (heteropolymers or bispecific monoclonal antibodies) used to bind prototype pathogens for targeting them and removing them for circulation see page 12. One of skilled in the art would have also been motivated to apply Taylor et al. monoclonal antibodies of that bind *Staphylococcus aureus* protein A for therapeutic purposes. (see Taylor et al. abstract). As to limitation of claim 76 antibodies 3F3, 2F9, 3F10 etc these monoclonal antibodies are well and commercially available. As to limitation of claim 73, PEG is also a well known crosslinking agent and commercially available.

Status of the Claims

10. Claims 1, 65-74 and 76 are rejected.

Claim 75 is objected to as being depending from rejected claim 1.

Claim 75 is free of prior art.

Conclusion

11. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is 571-272-0863. The examiner can normally be reached on Monday-Friday 7:30 AM-5:00 PM If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Khatol Shahnan-Shah. B.S.,
Pharm, M.S.
Biotechnology Patent Examiner
Art Unit 1645
March 28, 2008

/Shanon A. Foley/
Supervisory Patent Examiner, Art Unit 1645